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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|----------------------------------|-------------|-----------------------|---------------------|------------------|
| 10/050,216 | 01/16/2002 | Rory A.J. Curtis | MPI01-049P1RNM | 6278 |
| 7590 | | 07/01/2004 | EXAMINER | |
| Jean M. Silveri | | WALICKA, MALGORZATA A | | |
| Millennium Pharmaceuticals, Inc. | | ART UNIT | | |
| 75 Sidney Street | | PAPER NUMBER | | |
| Cambridge, MA 02139 | | 1652 | | |

DATE MAILED: 07/01/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

| | | | | |
|------------------------------|------------------------|--|---------------------|--|
| Office Action Summary | Application No. | | Applicant(s) | |
| | 10/050,216 | | CURTIS ET AL. | |
| | Examiner | | Art Unit | |
| | Malgorzata A. Walicka | | 1652 | |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-33 is/are pending in the application.
 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☐ Claim(s) ____ is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☒ Claim(s) 1-33 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. ____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s)/Mail Date. ____. |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date ____. | 6) <input type="checkbox"/> Other: ____. |

Restriction to one of the following inventions is required under 35 U.S.C. 121:

- I. Claim 1-11 and 23, drawn to an isolated nucleic acid molecule, vector, host cell and recombinant method of protein production, classified in class 435, subclass 252.3.
- II. Claim 12-18, drawn to protein, classified in class 435, subclass 226.
- III. Claim 19-22, drawn to antibody to protein of Group II, classified in class 530, subclass 387.9.
- IV. Claim 24-26, drawn to a method for detecting the presence of a polypeptide of claim 12, classified in class 435, subclass 7.1.
- V. Claim 27-29, drawn to a method of detecting a nucleic acid molecule of Group I classified in class 435, subclass 6.
- VI. Claim 30-33, drawn to a method for identification a compound that binds to a polypeptide of Group II, classified in class 435, subclass 4.
- VII. Claim 32, drawn to a method for modulating the activity of a polypeptide of Group II, classified in class 435, subclass 23.
- VIII. Claim 33, drawn to a method for identifying a compound which modulates the activity of a polypeptide of Group II, classified in class 435, subclass 23.

The inventions are distinct, each from the other because:

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Inventions of Group I, II and III are independent chemical entities having different structure biological functions and effects and, therefore, require separate search in the patent literature and publications.

Inventions of Group I and IV are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions are: Group I, i. e. to DNA encoding the metalloprotease and related subjects, and the method to detect said metalloprotease using, for example, specific antibody. Therefore, inventions of group I and IV are incapable of use together, i.e., they are unrelated.

Inventions of Group I and V are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions of Group I, i. e. expression of DNA in a transformed cell to produce a protein, and V, i.e. detection of said DNA by hybridization to an appropriate probe, have different modes of operation, functions and effects. Therefore, inventions of Group I and V are incapable of use together, i.e., they are unrelated.

Inventions of Group I and V are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case, invention of the product of Group I, i.e. DNA cannot be used with the method of detecting the presence of the polypeptide which it encodes.

Inventions of Group I and VII are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions of Group I, i. e. expression of DNA in a transformed cell to produce a protein, and VII, i.e. a method for modulating the activity of a polypeptide of Group II, have different modes of operation, functions and effects. Therefore, inventions of Group I and VII are incapable of use together, that is they are unrelated.

Inventions of Group I and VIII are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions of Group I, i. e. expression of DNA in a transformed cell to produce a protein, and VIII, i.e. a method for identifying a compound which modulates the activity of a polypeptide of Group II, have different

modes of operation, functions and effects. Therefore, inventions of Group I and VIII are incapable of use together, i.e., they are unrelated.

Inventions of Group II and IV are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case, invention of Group II, metalloprotease, may be used with a materially different process than its detection. For example, it may be used to perform catalysis in biochemical reaction for which it is specific. Thus, the invention of Group II and IV are distinct.

Inventions of Group II and V are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the invention of group II, the protein, a metalloprotease, is unrelated to the method of detection of DNA as claimed in Group V. Both inventions are disclosed as not capable of use together, and are therefore distinct.

Inventions of Group II and VI are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially

different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the product claimed in group II may be used in the process different than a method of group VI, i.e. identifying a compound which binds to the product. For example, the product, being an enzyme, may be used to perform catalysis in biochemical reaction for which it is specific. Thus, the inventions of Group II and VI are distinct.

Inventions of Group II and VII are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the product claimed in Group II, the enzyme, may be used in the process different than a method of Group VII, i.e. modulation of its activity. For example, it may be used for production of antibody. Thus, the inventions of Group II and VII are distinct.

Inventions of Group II and VIII are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the product claimed in Group II, the enzyme, may be used in the process different than a method of

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Group VIII, i.e. identifying a modulator of the enzyme activity. For example, it may be used for precipitation with its antibody. Thus, the inventions of Group II and VIII are distinct.

Inventions of Group III and IV are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case, the invention of Group IV, the method of detection of enzyme, may be practiced by detection of the biochemical reaction the enzyme catalyses, and not by precipitation of the enzyme with its antibody. Thus the inventions of Group III and IV are distinct.

Inventions of Group III and V, VI, VII, VIII are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the invention, the antibody against metalloprotease is unrelated to the methods of Group V-VIII, i.e. method of detecting the presence of DNA encoding metalloprotease, the method for identifying a compound which selectively binds to metalloprotease, the method of modulating of the activity of metalloprotease, a method for identifying a modulator of activity of metalloprotease. The considered inventions have different functions, modes of operation and effects, and are

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not capable of use together. The inventions of Group III and V-VIII are all different from each other.

Inventions of Group IV, V, VI, VII and VIII are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the invention claimed in Group IV, the method of detection of metalloprotease is unrelated to the methods of Group V-VIII, i.e. method of detecting the presence of encoding DNA, the method for identifying a compound which selectively binds to the enzyme, the method of modulation of the activity of said enzyme, a method for identifying a compound that modulates the activity of said. The considered inventions have different functions, modes of operation and effects. For that reasons they are not capable of use together. The inventions of Group IV and V-VIII are, therefore, all distinct from each other.

Inventions I-VIII are distinct for the reasons given above and have acquired a separate status in the art. Because of their recognized divergent subject matter and/or different classification and required searches, restriction for examination purposes as indicated is proper.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim

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remaining in the application. Any amendment of inventorship must be accompanied by a petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Malgorzata A. Walicka, Ph.D., whose telephone number is (571) 272-0944. The examiner can normally be reached Monday-Friday from 10:00 a.m. to 4:30 p.m. If attempts to reach examiner by telephone are unsuccessful, the examiner's supervisor, Ponnathapura Achutamurthy, Ph.D. can be reached on (571) 272-0928. The fax phone number for this Group is (571) 273-0937.

Malgorzata A. Walicka, Ph.D.

Patent Examiner

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PANNATHAPURA ACHUTAMURTHY
PATENT EXAMINER
RECEIVED JUNE 11 2008